

Implementation of NTP Approach by OHAT

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NTP Board of Scientific Counselors
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OHAT Process

Plan for Evaluation

Conduct Evaluation

Peer Review and Publish NTP Monograph

Invite topics for evaluation

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Public comment Interagency input

Prepare draft concept: topic and protocol (Step 1)



Review draft concepts by NTP Board of Scientific Counselors* (public meeting: public comment)



NTP Director

Prepare draft NTP Monograph (Steps 2-7)

- Search for and select studies (Step 2)
- Extract data (Step 3)
- · Assess individual study quality (Step 4)
- Rate confidence in body of evidence (Step 5)





Interagency

Public

- Translate confidence ratings into levels of evidence for health effects (Step 6)**
- Integrate evidence to develop hazard identification conclusions (Step 7)**



Interagency review

Complete draft NTP Monograph

Release draft NTP Monograph



Public comment

Peer review draft NTP Monograph by



or

Ad hoc reviewers (by letter review)

Present information regarding peer review to NTP Board of Scientific Counselors*



NTP Director

Publish final NTP Monograph

Finalize topic and start evaluation

Steps 1-7 refer to the NTP Approach; for details see http://ntp.niehs.nih.gov/go/38138

- * federally chartered advisory group
- ** not included in state of science evaluation

OHAT Process

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Public comment Interagency input

- general comments
- identify experts
- identify ongoing research
- comments on approach methods used to focus topic

• Rate confidence in body of evidence (Step 5)

Input on steps 2-5 as needed

- External scientific
- Public
- Interagency
- Translate confidence ratings into levels of evidence for health effects (Step 6)**
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Interagency review

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External scientific input Public comment Interagency input

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Protocol

- Background & objectives
- Methods
 - Literature search
 - types of studies, exposures, primary/secondary health outcomes, search terms, databases, screening strategy, conflict resolution
 - Data collection and analysis
 - study design features, results (effect size conversions), statistical power, risk of bias, factors considered when determining whether meta-analysis is appropriate
 - Confidence ratings & hazard ID (when appropriate)
 - how upgrade and downgrade factors will be assessed
- 25+ pages in length
- Obtain scientific input (technical advisors, BSC) and solicit public comment prior to implementing

Next Steps

- Release revised guidance ("working draft")
 - Public comment period
- Case studies to assess and refine methods
 - Interagency input
 - Release protocols for public comment
- Release finalized guidance
 - Public comment
 - Expect to be updated periodically as new methodology developed, e.g., framework for developing confidence ratings for *in vitro* and mechanistic data

Review Question

Please comment on the NTP's proposed plans for implementation of the NTP Approach in Office of Health Assessment and Translation literature-based evaluations.